IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. CHARLES ALCORN, BEATRICE MANNING and G. RAYMOND PIRONTI, JR.,	:	
Plaintiffs	:	
v.	:	CIVIL ACTION NO. 98-5688
SCHERING-PLOUGH CORPORATION,	:	
Defendant	:	

UNITED STATES' COMPLAINT-IN-INTERVENTION

Plaintiff, the United States of America, on behalf of the Department of Health and Human Services, files this Complaint-In-Intervention in substitution for and superseding the Relators' Amended Complaint and alleges as follows:

PARTIES

1. Plaintiff is the United States of America ("United States") on behalf of its agency, the Department of Health and Human Services ("HHS").

2. Defendant Schering-Plough Corporation ("Schering") is a New Jersey Corporation with its principal place of business in Kenilworth, New Jersey. At all relevant times, Schering was engaged in the manufacture sale and interstate distribution of a broad range of pharmaceutical products including the Claritin family of non-sedating antihistamines.

3. Relator Charles Alcorn is a citizen of the Commonwealth of Pennsylvania residing in Reading, Pennsylvania.

4. Relator Beatrice Manning is a citizen of the Commonwealth of Massachusetts residing in Stow, Massachusetts.

5. Relator Raymond Pironti, Jr. is a citizen of the State

of Florida residing in Palm Harbor, Florida.

6. Relators filed the qui tam Complaint on October 27, 1998. On May 28, 2004 Relators dismissed all defendants except Schering and all counts except certain counts against Schering. Relators filed their Amended Complaint on July 12, 2004.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345.

8. This Court has personal jurisdiction over the defendant as defendant transacts business in this District and defendant engaged in wrongdoing in this District.

9. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendant transacts business within this District.

BACKGROUND

10. The United States alleges violations of the Civil False Claims Act, as amended, 31 U.S.C. §§ 3729 et seq., the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b and violations of the common law for fraud, unjust enrichment and other violations of federal law and regulations and seeks damages, civil penalties, prejudgment interest and other legal and equitable remedies.

11. The allegations in this Complaint generally arise from the following illegal conduct by Schering:

(a) the knowing submission of false records or statements to the Centers for Medicare and Medicaid Services ("CMS") regarding the best price for the Claritin tablet family of drugs by failing to include the value of services, additional discounts, cash incentives and other arrangements given to two managed care customers from 1998 through 2002;

(b) abuse of the Medicaid Program and the Public Health Service Program to obtain unjust enrichment.

12. In 1965, Congress enacted Title XIX of the Social Security Act ("Medicaid" or the "Medicaid Program") to expand the nation's medical assistance program for the needy and medically needy aged, blind, disabled, and families with dependent children, 42 U.S.C. §§ 1396-1396v. The Medicaid Program is funded by both federal and state monies, collectively referred to as "Medicaid Funds," with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). Each State is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by HHS. 42 U.S.C. § 1396a. Among other forms of medical assistance, the States are permitted to provide medical assistance from the Medicaid Funds to eligible persons for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12).

13. HHS is an agency of the United States and is responsible for the administration, supervision and funding of the federal Medicaid Program. The Center for Medicare and

Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA") is a division of that agency that is directly responsible for administering the federal Medicaid Program, including review and approval of the individual State medical assistance plans.

14. In 1990, Congress enacted the Medicaid Rebate Program, 42 U.S.C. § 1396r-8. Under this program, each drug manufacturer voluntarily entered into an agreement with CMS in which it agreed to pay rebates to the States based on the utilization of its drug products in exchange for having those drug products covered by the State plans and reimbursed through Medicaid Funds. 42 U.S.C. § 1396r-8(a)(1).

15. Under the Medicaid Rebate Program and the rebate agreement with CMS, among other responsibilities, a participating drug manufacturer was required:

> (a) to report to CMS on a quarterly basis its "best price" for single source and innovator multiple source drugs, defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the United States," with certain specified statutory exclusions. 42 U.S.C. § 1396r-8(c)(1)(C)(1);
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> (b) to pay to each State plan a quarterly rebate with respect to single source and innovator multiple source drugs equal to the product of (a) the units of each

dosage form and strength paid for under the State plan during the rebate period as reported by the state, and (b) the greater of (i) the difference between the average manufacturer price and the best price, or (ii) a minimum rebate percentage of the average manufacturer price. 42 U.S.C. § 1396r-8(c)(1)(A).

16. At all relevant times Schering was subject to a rebate agreement with the CMS, and Schering's drug products were at all relevant times covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396(a)(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with CMS, Schering agreed: (i) to report quarterly to CMS its average manufacturer price and best price for its drug products; and (ii) to pay quarterly rebates to the states as described above.

17. In 1992, Congress enacted Section 340B of the Public Health Service ("PHS") Act, known as the Drug Pricing Program, to provide drug price protection for certain PHS entities that receive federal funds. 42 U.S.C. § 256b. PHS entities include such safety net programs as black lung clinics, State operated AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, and disproportionate share hospitals, all as further defined in the Drug Pricing Program. 42 U.S.C. § 256b(a)(4).

18. At all relevant times, Schering participated in the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the

Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300GG-92. As a participant in the Drug Pricing Program, Schering entered into an agreement with HHS in connection with the pricing of its drug products sold to PHS entities as described above. Under the Drug Pricing Program and its agreement with HHS, Schering generally agreed that the amount that Schering required the PHS entities to pay for drug products would not exceed the average manufacturer price, as reported by Schering to CMS in the previous calendar quarter, minus a specified rebate percentage that was derived in part from the Medicaid rebate paid by Schering in the preceding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a).

FACTUAL ALLEGATIONS

19. At all relevant times Schering marketed a broad range of drugs with Schering's largest selling prescription products being the Claritin family of non-sedating antihistamines.

20. At all relevant times Schering employed a range of strategies to gain and maintain access to managed care customers' formularies in order to sell its drugs to these customers.

MANAGED CARE CUSTOMER 1

21. During the course of 1996 and 1997, Schering and Managed Care Customer 1 entered into agreements that were to govern the pricing on all of the Schering drugs on the Managed Care Customer's formulary including the Claritin tablet family of

products. The agreements each had terms of three years.

22. In 1998, Managed Care Customer 1 experienced an unanticipated increase in costs due to an increase in use of Claritin as a result of Schering's direct-to-consumer advertizing. It asked Schering to increase its Claritin discounts and rebates and when Schering refused, Managed Care Customer 1 voted to remove the Claritin tablet family of drugs from its formulary (including the main Claritin tablet product, two Claritin/decongestant tablet products, and a rapidly dissolving form of Claritin tablet called a "Reditab").

23. At all relevant times Schering was aware that providing the specific additional Claritin discounts and rebates Managed Care Customer 1 was requesting would have required Schering to report lower Claritin best prices to the government which would have resulted in increased rebates going to Medicaid.

24. Schering ultimately agreed to provide Managed Care Customer 1 with a package of additional payments and services including:

(a) annual cash payments of approximately $2.5 million that were described as "data processing fees" in exchange for Managed Care Customer 1's agreement to provide Schering with annual reports that were already contractually required to be provided and were never used;

(b) $3 million in discounts on Managed Care Customer 1's staff model purchases of Claritin Reditabs, a

rapidly dissolving form of the Claritin tablet;

(c) interest-free loans through pre-paying rebates owed under its 1997 agreements;

(d) health management contracts, expanding the range of health management services it was providing to Managed Care Customer 1 and extending its health management programs to additional regional sites while charging Managed Care Customer 1 a rate well below fair market value.

25. At all relevant times Schering knew the value of these additional payments and services were hidden Claritin discounts. It knowingly excluded these discounts from its determination of the reported best price for the Claritin tablet family of products.

Managed Care Customer 2

26. During the course of 1995 through 1997, Schering and Managed Care Customer 2 entered into agreements that were to govern the pricing on all of the Schering drugs on Managed Care Customer 2's formulary including the Claritin tablet family of products.

27. In 1998, Managed Care Customer 2 experienced an increase in costs due to an increase in use of Claritin as a result of Schering's direct-to-consumer advertizing. It threatened to remove the Claritin tablet family of drugs from its formulary unless substantial additional discounts were provided.

28. At all relevant times Schering was aware that providing

Managed Care Customer 2 the specific additional Claritin discounts and rebates Managed Care Customer 2 was requesting would have required Schering to report lower Claritin best prices to the government which would have resulted in increased rebates going to Medicaid.

29. Schering ultimately agreed to provide Managed Care Customer 2 with a package of additional payments and services including:

(a) interest-free loans through prepaying rebates;

(b) deep discounting or "nominal" pricing on certain Schering products';

(c) a "risk share" arrangement under which Schering agreed to cover a portion of Managed Care Customer 2's annual antihistamine costs such that in any year in which Managed Care Customer 2's total antihistamine costs increased by more than 10% then Schering became responsible for all antihistamine cost increases up to a cap of 25% of the prior year's costs. For 1998, 1999, and 2000, Schering paid a total of approximately $25 million pursuant to this "risk share" provision alone;

(d) implementation of two pilot health management programs at Managed Care Customer 2's sites including a "Seniors Health and Wellness" demonstration project and a member retention internet-based health management project charging Managed Care Customer 2 a rate well

below fair market value.

30. At all relevant times Schering knew that the value of these additional payments and services were hidden Claritin discounts. It knowingly excluded these discounts from its determination of the reported best price for the Claritin tablet family of products.

31. From the First Quarter of 1998 through the Fourth Quarter of 2002, Schering knowingly misreported its best prices to CMS for the Claritin tablet family of drugs by failing to include the value of the above arrangements with these 2 Managed Care Customers as additional discounts on such drugs resulting in the unlawful denial of these price reductions to the Medicaid Program.

32. From the First Quarter of 1998 through the Fourth Quarter of 2002, Schering overcharged the PHS entities for the Claritin tablet family of drugs by failing to include the value of the above arrangements in the calculation of pricing to which the PHS entities were entitled.

33. The specific Claritin National Drug Code numbers affected are 00085-0458 (Claritin Tablets), 00085-0635 (Claritin D-12), 00085-0640 (Claritin D-24), 00085-1233 (Claritin D-24), 00085-1128 (Claritin Reditabs).

COUNT ONE
False Claims Act, 31 U.S.C. § 3729(a)(7)
(Knowingly Making or Using a False Statement to Avoid or Conceal Obligations)

34. Plaintiff realleges and incorporates herein by reference each and every allegation set forth in paragraphs 1 through 33.

35. Schering knowingly made and used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Government.

36. By virtue of the false records or statements made or used by Schering, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false statement made or used by the defendant.

COUNT TWO
Common Law Fraud

37. Plaintiff realleges and incorporates herein by reference paragraphs 1 through 36.

38. Schering knowingly and intentionally made or caused to be made false statements of material facts to CMS and thus to the United States, with knowledge of their falsity and with fraudulent intent, to mislead the United States, and upon which the United States reasonably relied to its injury.

39. In reliance on said false statements by Schering, the United States has suffered damages in an amount to be determined at trial.

COUNT THREE
Unjust Enrichment

40. Plaintiff realleges and incorporates herein by reference paragraphs 1 through 39.

41. This is a claim for the recovery of monies by which Schering has been unjustly enriched.

42. As a result of the facts alleged in this Count, Schering has maintained control over certain monies to which it is not entitled.

43. By maintaining monies to which Schering was not entitled, Schering unjustly enriched, and is liable to account and pay such amounts or the proceeds therefrom, to be determined at trial, to the United States.

WHEREFORE, the United States demands and prays that judgment be entered in favor of the United States and against Defendant Schering as follows:

A. On Count One, under the False Claims Act, as amended, for treble of the amount of the United States damages and civil penalties as required by law, together with such further relief as may be just and proper.

B. On Counts Two and Three, for the damages sustained, plus interest including prejudgment interest costs, an accounting and such further relief as may be just and proper.

Respectfully submitted,

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